REMARKS

Claims 1-21, 24, and 25 are presented for the Examiner's review and consideration. In this Response, Applicant has amended claim 9 and claims 22 and 23 have been cancelled. Applicant believes that the claim amendment, cancellations, and the accompanying remarks serve to clarify the present invention and are independent of patentability. Accordingly, Applicant respectfully submits that that they do not limit the range of any permissible equivalents.

In the Drawings

The Examiner objected to the drawings. Specifically, the Examiner stated that Figure 1 does not show passage 32 formed partially in the body and partially in the pointed end portion since it appears that the pointed end portion begins below the boundary between the body portion and the pointed end portion and separate from passage 32. The Examiner further states that it must be clear as to where the boundary is between the body portion and the pointed end portion.

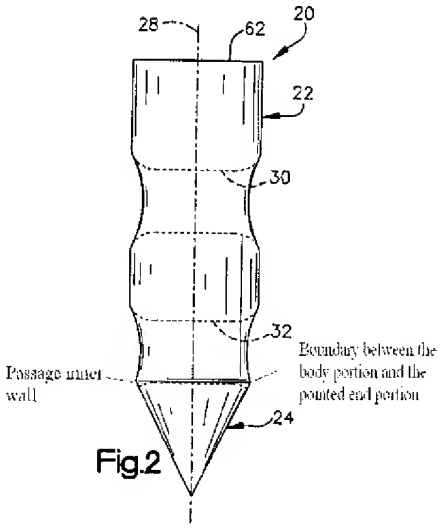


Fig.2

Referring to Figure 2, the boundary between the body portion and the pointed end portion is clearly shown. Similarly, the inner wall of the passage is shown, being shown with dotted lines. The inner wall of the passage is shown below the boundary between the body portion and

the pointed end portion, and as such, the passage is clearly shown as being formed partially in the body and partially in the pointed end portion. Support can also be found in the specification. Specifically, ¶[0033] provides "the passage 32 is formed partially in the body section 22 and partially in the pointed end portion 34."

In light of the foregoing, Applicant requests reconsideration and withdrawal of the objection to the drawings.

35 U.S.C. § 102 Adams

Claims 9-11 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,099,552 Adams ("Adams"). For the reasons set forth below, Applicant respectfully submits that the rejected claims are not taught or suggested by Adams.

Adams relates to compression clips, and more specifically, to compression clips used to cause hemostasis of blood vessels located along the gastrointestinal tract. (Col. 1, lns. 4-7). Mechanical hemostatic devices are used in various parts of the body, including GI applications. (Col. 1, lns. 24-25). Such devices are typically in the form of clamps, clips, staples, sutures, etc., which are able to apply sufficient constrictive forces to blood vessels so as to limit or interrupt blood flow. (Col. 1, lns. 25-28).

In a first embodiment of Adams as shown in FIG. 1, medical device 100 includes a stem 101 having first end 102 and second end 103. (Col. 2, lns. 36-38). Stem 101 has at least one transverse hole 104 therein of any suitable shape (e.g. circular, rectangular, square, etc.). (Col. 2, lns. 38-40). Stem 101 is further characterized by an anchor 105 at its first end 102. (Col. 2, lns. 40-41). Medical device 100 also comprises a bolster 106, which includes a flap 107 adapted to be inserted into hole 104. (Col. 2, lns. 42-44).

In use, stem 101 is pushed out of sleeve 403 by stem pusher 404 such that the first end 102 of stem 101 pierces the GI wall 410, as shown in FIG. 5C. (Col. 3, lns. 56-59). Once stem 101 is extended to a desired depth within GI wall 410, bolster pusher 406 is used to push bolster 106 over stem 101 and towards first end 102. (Col. 3, lns. 60-61). As bolster 106 proceeds towards first end 102, an increasing pressure is applied to the tissue between GI wall 410 and

anchor 105. (Col. 3, lns. 61-63). Anchor 105 is thus urged back towards GI wall 410, resulting in the expansion of anchor 105 to its "unfolded" configuration and thus locking stem 101 in its position as shown in FIG. 5D. (Col. 3, lns. 63-66). When sufficient pressure is applied to the GI wall 111 to cause hemostasis of an adjacent bleeding blood vessel, flap 107 of bolster 106 is locked into the at least one transverse hole 104 in stem 101. (Col. 3, ln. 67 – col. 4, ln. 3). As such, bolster 106 maintains pressure of the GI tissue and permanently induces hemostasis of the adjacent blood vessels. (Col. 4, lns. 3-5).

As such, Adams discloses a compression device for causing hemostasis of blood vessels located along the gastrointestinal tract. The device includes a stem having an anchor on one end and transverse holes there along. A bolster is slidably positioned over the stem, where the bolster includes a flap to engage in a transverse hole. The device of Adams is inserted into a GI wall were the bolster is used to compress the portion of the GI wall between the anchor and the bolster. The bolster is locked into position by the tap engaging a transverse hole.

Accordingly, Adams is unrelated to securing a suture relative to a body tissue in a patient's body and therefore does not anticipate claim 9.

In order to expedite prosecution of the present application and clarify the invention, claim 9 now recites, *in part*, a device for securing a suture relative to a body tissue in a patient's body including a first opening defining a first passage formed partially through the cylindrical body and partially through the pointed end portion in a direction transverse to the longitudinal central axis of the cylindrical body.

Applicant submits the Adams does not disclose, contemplate, or suggest having a a suture securing device as set forth in claim 9. In light of the foregoing, claim 9 is respectfully submitted to be patentable over Adams. As claims 10 and 11 depend from claim 9, and necessarily include all the elements of the base claim, Applicant respectfully submits that these dependent claims are also patentable over Adams at least for the same reasons.

35 U.S.C. § 103

Claims 1-3 and 8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S.

Patent No. 5,540,718 to Bartlett ("Bartlett") in view of U.S. Patent No. 4,235,238 to Ogiu et al. ("Ogiu"). For the reasons set forth below, Applicant respectfully submits that the rejected claims are patentable over Bartlett in view of Ogiu.

The Examiner stated that Bartlett discloses the claimed device except for one of the passages being formed partially in the body portion and partially in the pointed end portion. The Examiner further stated that Ogiu teaches a tissue suturing apparatus with a passage used for threading suture that is formed partially in the body portion 1 and partially in the pointed end portion 3 (Figure 51).

As discussed in the previous Response to Office Action, Bartlett discloses that anchors could have potential cross-sectional bores including oblong, elliptical, tear-drop, a figure eight (thereby providing separate bores for the suture and the insertion tool.) (Col. 5, lns. 34-37). Suture 64 may be threaded through bore 34 of the suture anchor in any preferred manner such as those illustrated in FIGS. 6-8. (Col. 6, lns. 35-37).

Ogiu relates to a suturing apparatus conducted into a body cavity through an endoscope to suture tissues around a bleeding portion in the body cavity. (Col. 1, lns. 5-8). It is accordingly the object of Ogiu to provide a coeliac tissue-suturing apparatus in which a needle is conducted through an endoscope into a body cavity to suture a broad coeliac bleeding spot, thereby unfailing carrying out a hemostatic operation. (Col. 1, lns. 37-42).

The coeliac tissue-suturing apparatus of Ogiu comprises a flexible tubular member 1 constructed by winding a flexible wire such as stainless steel in the coil form. (Col. 3, lns. 41-44). The distal end of the tubular member 1 is securely fitted with the rear end of a substantially cylindrical stainless steel needle 3 provided with a sharp tip 3a. (Col. 3, lns. 44-47). Formed in the body of the needle 3 is a first-stop receiving chamber 6 which is opened to the outside at the lateral opening 4 of the needle 3 and communicates with the interior of the tubular member 1 or a cylindrical passage 5 through a cylindrical passage 10 formed in the rear end of the needle 3. (Col. 3, lns. 51-56).

That end of a suturing thread 9 extended along the peripheral surface of the tubular member 1 which faces the needle 3 is fastened to a first pillar like or cylindrical stop 7 in a state

inserted into an annular groove 8 formed at the center of the first stop 7. (Col. 3, lns. 60-64). The first stop 7 is received in the receiving chamber 6, such that the rear end of the stop 7 is inserted into the passage 10, thereby preventing the stop 7 from naturally coming off. (Col. 3, lns. 64-68).

Inserted into the tubular member 1 is a flexible pushing rod 11 made of, for example, a stainless steel wire. (Col. 4, lns. 1-2). The distal end of the pushing rod 11 inserted into the tubular member 1 pushes the first stop 7, which in turn slides up the inclined wall 6a of the first-stop receiving chamber 6 to protrude out of the needle 3 through its lateral opening 4 as shown in FIG. 5. (Col. 4, lns. 5-10).

Coeliac tissue-suturing apparatuses according the embodiments of FIG. 45 and following drawings illustrate a continuous multistitch suturing operation. (Col. 10, lns. 58-60). The needle 3 and adjacent tubular member 1 have a construction similar to those of the suturing apparatus of FIG. 1. (Col. 10, lns. 62-64). The difference is that the passage 5 of the tubular member 1 receives solid cylindrical intermediate stops 74 each having a cross bore 75 formed in the middle portion thereof; and the suturing thread 9 whose distal end is fastened to a first stop 7 is extended through the bores 75 of the intermediate stops 74 and then runs through a flexible stop pushing tube 76 inserted into the tubular member 1 and finally out of the proximal end of an endoscope. (Col. 10, ln. 64 – col. 11, ln. 4).

FIGS. 46 to 50 indicate the initial stitch process of suturing tissues around a coeliac bleeding spot by the suturing apparatus of FIG. 45. (Col. 3, lns. 15-17). FIG. 51 shows the second stitch process of suturing the tissues. (Col. 3, lns. 18-19).

As such, Ogiu discloses a needle (3) which is fitted onto a tubular member (1). The needle includes a passage and a lateral opening through which a suture stop (7) can be pushed, where the suture stop is connected to the suture. In addition to suture stop, intermediate stops can be pushed through the needle, where an intermediate stop has a cross bore formed at its mid portion. The suture and intermediate stops are used to secure the suture relative to the body tissue in the patient's body, and are each shown as being cylindrical in form, lacking a pointed end portion.

Accordingly, Ogiu fails to overcome the deficiencies of Bartlett, only disclosing an

insertion needle having a passage and a lateral opening for dispensing the suture and intermediate stops into the body of the patient, and fails to disclose a suture retaining device having a pointed end portion with a passage there through.

In light of the foregoing, claim 1 is respectfully submitted to be patentable over Bartlett in view of Ogiu. As claims 2, 3, and 8 depend from claim 1, and necessarily include all the elements of the base claim, Applicant respectfully submits that these dependent claims are also patentable at least for the same reasons.

Claims 12-21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Adams. For the reasons set forth below, Applicant respectfully submits that the rejected claims are patentable over Adams.

Initially, claims 12-20 depend from claim 9, and necessarily include all the elements of the base claim. As previously discussed, claim 9 is submitted to be patentable over Adams. Accordingly, Applicant respectfully submits that these dependent claims are also patentable at least for the same reasons.

With regard to claim 21, Adams discloses that the medical devices of Adams are made from any suitable biocompatible polymeric or metallic material. (Col. 2, lns 46-48). It is preferred, however, that stem 101 be made from an elastic material such as stainless steel, nitinol, or any suitable polymeric material such as polyethylene. (Col. 2, lns 48-48-50). The elasticity of stem 101 permits anchor 105 to be compressed to facilitate delivery within a body lumen. (Col. 2, lns. 50-52)

As such, the device of Adams is made of an elastic material to allow the anchors to be compressed to facilitate delivery.

In contrast, the present invention discloses that the anchor 20 is formed of a single piece of bone, specifically, hard compact bone. (¶[0026]). Hard compact bone is not an elastic material, and would prevent the compression of the anchors.

Accordingly, Applicant submits that Adams does not contemplate, suggest, or provide motivation for making the device out of bone.

In light of the foregoing, claim 21 is respectfully submitted to be patentable over Adams.

Claims 22 and 23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Adams in view of Ogiu.

Initially, claims 22 and 23 have been cancelled rendering the rejection of these claims moot. As previously noted, claim 9 has been amended to include the elements of claim 23. Applicant submits that amended claim 9 is patentable over Adams in view of Ogiu for the following reasons.

The Examiner stated that Adams discloses the claimed invention except for one of the passages being formed partially in the body portion and partially in the pointed end portion.

As set forth above, Ogiu only discloses an insertion needle having a passage and lateral opening for dispensing the suture and intermediate stops into the body of the patient, and fails to disclose a suture retaining device having a pointed end portion with a passage there through. As such, Ogiu fails to overcome the deficiencies of Adams.

Furthermore and as previously discussed, Adams does not disclose, contemplate, or suggest having a transverse hole formed partially through the stem and partially through the anchor, as the anchor would prevent the bolster flap from engaging such a hole, rendering the device inoperable for its intended purpose.

In light of the foregoing, claim 9 is respectfully submitted to be patentable over Adams in view of Ogiu.

Claims 24 and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Adams in view of Bartlett and U.S. Patent No. 6,368,343 to Bonutti et al. ("Bonutti"). For the reasons set forth below, Applicant respectfully submits that the rejected claims are patentable over Adams in view Bartlett and Bonutti.

Initially, Applicant notes that the present Application claims priority to Bonutti. As a result, Bonutti does not qualify as prior art. Furthermore, claims 24 and 25 depend from claim 9, and necessarily include all the elements of the base claim. As previously discussed, claim 9 is

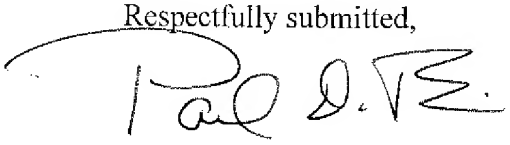
submitted to be patentable over Adams. Accordingly, Applicant respectfully submits that these dependent claims are also patentable at least for the same reasons.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No Fee is believed due. However, please charge the required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A03-003-1).

Respectfully submitted,



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